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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,998	09/18/2003	J. Oliver Dolly	17259-CON (B07)	1940

7590
Carlos A. Fisher
ALLERGAN, INC.
T2-TH
2525 Dupont Drive
Irvine, CA 92612

06/20/2007

EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/667,998

Applicant(s)

DOLLY ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed April 11, 2007 (hereinafter referred to as "the response") has been entered. Claims 1-5 have been amended and Claim 26 has been newly added.

Applicants' election without traverse of Group I, Claims 1-11 and 25, was acknowledged in the Office Action of January 17, 2007. The elected invention is directed to a method for extending the effective time period during which tissue treated with a clostridial toxin is paralyzed comprising administering a composition comprising an agent able to prevent the neuroregenerative activity of a polypeptide as recited in the claims (various neurotrophic factors). Applicants further elected the species IGF-1, from among the various polypeptides, and the species of a binding protein other than an antibody, from among the various agents.

The restriction requirement was made final.

Claims 1-5 and 26 are examined herein. The claims are examined herein only to the extent that they encompass the elected subject matter. No generic claims remain.

The rejection of Claims 1-6, 10, 11, and 25 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, is withdrawn in view of the amendments to the claims and the cancellation of Claims 6, 10, 11, and 25.

The rejection of Claims 1-6, 10, 11, and 25 under 35 U.S.C. 112, first paragraph, for failing to provide an enabling disclosure for the full scope of the claims, is withdrawn in view of the amendments to the claims and the cancellation of Claims 6, 10, 11, and 25.

It is noted that, at page 4 of the response, Applicants assert that one of skill in the art would know how to make a modified BoNT/A with a decreased biological persistence comprising a mutation in any

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amino acid in SEQ ID NO: 15. However, Applicants' comments do not pertain to the rejection of record or to the presently claimed invention. Thus, the comments are moot and are not further addressed herein.

Claim Objections

Claims 1-5 remain objected to and newly added Claim 26 is objected to for encompassing non-elected subject matter. In view of the rejection of the generic claims (see Office Action of 1/17/07), non-elected species should be deleted from the claims. Following an election of species requirement, when no generic claim is finally held to be allowable, the claims are restricted to the elected species. Appropriate correction is required. Applicants have not addressed this objection.

As set forth in MPEP § 809.02(a), when no generic claim is finally held to be allowable, the claims shall be restricted to the elected species. In the instant case, the rejections of record, as set forth at pages 3-7 of the Office Action mailed January 17, 2007, demonstrate that the generic claims are not allowable. Applicants elected the species IGF-1, but the present claims are directed to inhibiting IGF-2, in addition to IGF-1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 and 26 are indefinite in their recitation of "extending the effective period during which tissue treated with said clostridial neurotoxin is paralyzed" because it is unclear relative to what standard or point of reference the period of paralysis is considered to be "extended." The term

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"extending" is a relative term which renders the claim indefinite. The term "extending" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, the metes and bounds are not clearly set forth.

The claims have been amended to recite the conclusory statement "thereby extending the effective period during which tissue treated with said clostridial neurotoxin is paralyzed." The specification teaches that this "extended" period of paralysis is relative to the result obtained with clostridial toxin alone. It is unclear what other point of reference could be used.

The enablement rejection set forth at page 4 of the Office Action mailed 1/17/07 acknowledged enablement "for the use of IGF-BP4 to bind and inhibit the activity of IGF-1 in the claimed method for extending the effective period during which tissue treated with a clostridial toxin is paralyzed, wherein said tissue is contacted with a composition comprising IGF-BP4 and a clostridial neurotoxin effective to extend the period of paralysis as **compared to treatment with clostridial toxin alone**" (emphasis added). This language would be remedial.

Claim 5 is indefinite in its recitation of "said botulinum neurotoxin" because the phrase lacks antecedent basis. Claim 1 does not recite a "botulinum neurotoxin."

Conclusion

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing

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date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/
Primary Examiner, Art Unit 1632